REMARKS

1. Claims 1 and 5 have been amended; claims 6-15 were previously withdrawn. Basis for these amendments exists in claim 5 as originally filed. No new matter has been added.

As Claim 5 has been before the Examiner since the case was originally filed and is now specifically rejected, it is respectfully submitted that this amendment to incorporate the limitations of claim 5 into claim 1 raises no new issues, and thus there should be no prejudice in entering this amendment for purposes of appeal, if following consideration of the following remarks, the Examiner is nevertheless unwilling to allow the claims.

2. Claims 1-5 are rejected under 35 U.S.C §112 for lack of enablement. The Examiner argues "given that eotaxin itself is an inflammatory mediator, it would be unpredictable how a method of treating an inflammatory condition such as asthma using eotaxin can be practiced." The claims are amended to make clear that what is to be administered is not eotaxin per se but rather an immunogenic composition comprising eotaxin or a portion of eotaxin bound to an immunogenic carrier.

Applicant reiterates that, for the reasons stated in the previous response to office action, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention (*In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995)), and that burden is not met in this case.

There is simply no reason to expect that an immunogenic composition comprising eotaxin or a portion of eotaxin bound to an immunogenic carrier would have a biological activity similar to eotaxin alone, or that there would be unusual problems with the generation of the immune response in this case which are not adequately addressed by the teachings of the

specification. The rejection under 35 U.S.C. §112 should therefore be withdrawn.

3. Claims 1-5 are rejected under 35 U.S.C. §102(b) for lack of novelty over McDonald, et al. To avoid any ambiguity, Applicant has amended the claims to make clear that what is administered in the methods claimed is not eotaxin, nor eotaxin linked to a cytotoxic agent, but rather an immunogenic composition comprising eotaxin or a portion of eotaxin bound to an immunogenic carrier.

Applicant respectfully reiterates that the compounds of McDonald, although having some structural features in common with the immunogenic conjugates of the present invention, are not and are not intended to be immunogenic conjugates. Rather, they are intended to be cytotoxic drugs, "magic bullets" for killing cells. Eotaxin is identified as a possible ligand, among a host of other cytokines. The compounds of McDonald are generally fusion proteins or otherwise prepared to contain a single moiety of ligand (e.g. eotaxin) linked to a toxin, in contrast to the immunogenic conjugates of the invention herein, which are chemically crosslinked to a large toxin molecule, so that the toxin molecule might contain many moieties of antigen, thereby enhancing its immunogenic potential. The compounds of McDonald are formulated and delivered differently, presumably using biologically neutral pharmaceutical excipients rather than immunogenic adjuvants. They would not be suitable for use in the methods claimed in the instant application, because an immunogenic effect would be neither expected nor desired. The Examiner's statement that "the same patient is being administered the same eotaxin by the same mode of administration" is factually incorrect.

The Examiner speculates, without any further evidence, that administration of the cytotoxic agents disclosed by McDonald might nevertheless *inherently* result in production of

autoantibodies. Inherency, however, for purposes of 35 U.S.C. §102, "may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Continental Can Co. v. Monsanto Co.* 948 F.2d 1264, 1269 (Fed. Cir. 1991)(emphasis in original). As the Examiner has provided no evidence whatsoever that administration of compounds as disclosed in McDonald in the manner described by McDonald would *necessarily* result in an immunogenic response as claimed, this rejection on the grounds of inherent anticipation should be withdrawn.

4. Claims 1-5 are rejected under 35 U.S.C. §102(e) for lack of novelty over Bachmann, et al. This is a new ground for rejection and is therefore wholly improper in a final office action. Bachmann was previously cited under 35 U.S.C. §102(b), and Applicant properly responded to that rejection on the grounds that Bachmann was published too late to be available as a reference under 35 U.S.C. §102(b). Rather than withdraw the rejection, however, the Examiner has changed the statutory basis for the rejection and made the rejection final, without giving Applicant an opportunity to respond with arguments relevant to 35 U.S.C. §102(e).

Applicant notes that the Bachmann filing claims the following priority:

> The present application claims the benefit of the filing dates of U.S. Provisional Appl. Nos. 60/331,045, filed Nov. 7, 2001, and 60/396,636, filed Jul. 19, 2002. The present application also is a continuation-in-part of, and claims priority to, U.S. patent application Ser. No. 10/050,902, filed Jan. 18, 2002, and International Appl. No. PCT/IB02/00166, filed Jan. 21, 2002, the latter of which was published under PCT Article 21(2) in the English language as WO 02/056905 on Jul. 25, 2002.

A review of the earliest claimed priority, USSN 60/331,045, filed November 7, 2001, however, reveals that this filing focused on the use of virus-like particles to form immunogenic conjugates; it does not appear to mention eotaxin at all. Eotaxin appears to be first mentioned in USSN 10/050,902, filed January 18, 2002, e.g., on page 56, as one of a great many possible antigenic

determinants, but only in connection with "compositions and methods of treatment for other diseases or conditions associated with self antigens. . . ." The disclosure of WO 02/056905 filed January 21, 2002 is very similar. Vaccines directed to eotaxin are not identified or suggested in these applications for use in the treatment of asthma, allergy or allergic disease.

The disclosure upon which the Examiner evidently relies for purposes of the rejection under 35 U.S.C. §102(e) appears only first in USSN 60/396,636, filed July 19, 2002, *after* the March 25, 2002 priority date of the instant application. This more extensive disclosure is unavailable as art against this application under 35 U.S.C. §102(e).

As relevant disclosure of Bachmann prior to the March 22, 2002 effective filing date of the instant application does not disclose or suggest methods for treating patients suffering from asthma, allergy or allergic disease using vaccines directed to eotaxin, such as are claimed in the instant case, the rejection under 35 U.S.C. §102(e) should be withdrawn.

5. Reconsideration and withdrawal of the pending objections and a speedy allowance of the claims submitted is respectfully requested. The Examiner is invited to contact the undersigned attorney for the Applicant in the event of any questions or it the Examiner believes that a telephone discussion could be useful in resolving any open issues.

Respectfully submitted,

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By: _____

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